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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,284	03/12/2004	Rob Barber	674523-2033	8663

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EXAMINER	
MCGILLEM, LAURA L	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/799,284	BARBER ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14,16-18 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14,16-18 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

It is noted that claims 1-4, 6-10, 12-14, 16-18 and 20 have been amended and claims 15, 19 and 21-24 have been cancelled in the amendment filed 05/12/2006. Claims 1-14, 16-18 and 20 are under examination.

Specification

It is noted that an Application Data sheet and an amended Abstract have been filed 05/12/2006. Therefore, the objections to the Oath and the Specification have been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14, 16-18 and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The rejection is being maintained for reasons of record in the previous Office action, mailed 12/15/2005 and for reasons outlined below.

Applicants submit that the claim amendments sufficiently define the scope of the claims such that they are enabled. Applicants submit that the invention is not an NOI *per se*, rather the invention is the treatment of pain through lentiviral mediated delivery of the NOI to a dorsal root ganglion cell.

Applicants' arguments, filed 05/12/2006, have been fully considered but they are not persuasive.

The amendments to claim 1 limit the claim to a method of treating chronic pain instead of treating or preventing pain of any type. Amendments also include the limitation that a lentiviral vector comprising an nucleotide of interest (NOI) is administered to a DRG cell in the subject wherein the expression of the NOI treats pain in the subject.

Although limiting the method to treatment of chronic pain rather than treatment and prevention of any type of pain does limit the scope of the claimed method somewhat, the claimed method remains insufficiently described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. It is understood that the claimed invention is a method of treatment of pain through lentiviral mediated delivery of the NOI to a dorsal root ganglion cell and not drawn to a product NOI. However, the lentiviral vector comprising the NOI is an element of the claimed method and the skilled artisan must be able to practice the method from the disclosures in the application coupled with information known in the art and know how to use the lentiviral vector comprising the NOI in the practice of the claimed method for treatment of chronic pain. The amendments to the claims and Applicants' arguments do not

address art recognized issues related to use of lentiviral vector delivery systems regarding potential immunogenicity, delivery specificity and potential for insertional mutagenesis of oncogenes. Although the EOI has now been limited by amendment to an NOI, and the specification provides examples of introduction of a potassium channel and a sodium channel protein, as the claim is written, the NOI for treatment of chronic pain is still broad in scope encompassing any nucleotide of interest that is expressed to treat pain in a subject. Therefore the skilled artisan would not know how to use this method of treating chronic pain without undue trial and error experimentation.

Claims 16-18 and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for identification or validation of an NOI for treatment of pain *in vivo*, does not reasonably provide enablement for methods for identification or validation of an EOI for treatment or pain *in vitro*. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Claim 20 has been newly added to this rejection because it is dependent on claim 18, which is dependent on claim 16. Previously the scope of claim 16 and therefore claim 20 included an enabled *in vivo* embodiment only. Since claim 16 has now been amended so that it now comprises the step of delivering a test NOI to a cell *in vitro*, claim 20 is included in the rejection.

Applicants submit that the claim amendments clarify that an identification or validation method is performed *in vivo*, after an initial screening step *in vitro*. Applicants

submit that examples of *in vitro* testing are known in the art and are provided in the specification. For example, Applicants submit that excitability of cells can be measured *in vitro* as changes in transmission (page 49, lines 30-33 and page 50, lines 6-8)

Applicants' arguments, filed 05/12/2006, have been fully considered but they are not persuasive.

Examples of *in vitro* testing are known in the art, including measurement of changes in cell excitability. The specification provides an example of lowered resting membrane potentials in DRG cells *in vitro* that have been transduced with a potassium channel (see paragraph 0330). However, the claim recites analyzing the effect of the test NOI on "pain avoidance or relief *in vitro*" which implies that an cultured cell would feel pain in order to be able to avoid pain or feel relief from pain. As discussed in the original rejection, pain and the ability to sense pain, avoid pain and feel relief from pain are extremely complex mechanisms that require the sensory nervous system of a multicellular organism. As the claim is written, it appears that a single *in vitro* cultured cell would have to be able to recognize the sensation of pain and be able to avoid pain in some manner, presumably through some response mechanism. The claim does not recite analyzing the effect of a NOI on cell resting membrane potentials or excitability; it recites the limitation of "pain avoidance or relief". The specification does not provide information regarding how to measure pain, as it is claimed in a cultured DRG. Therefore the skilled artisan would not know how to practice the claimed method for identification or validation of a NOI useful in the treatment of pain without undue trial and error experimentation.

The rejection of claim 4 under 35 U.S.C. 112, first paragraph, written description has been withdrawn because claim 4 has been amended.

The rejection of claim 18 under 35 U.S.C. 112, second paragraph, indefiniteness has been withdrawn because claim 18 has been amended to remove the phrase "derived from".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of copending Application No. 10/837,130 in view of Carpenter (Core text of Neuroanatomy, 4th Ed.1991, pages 75-

76). This is a NEW REJECTION made in light of the 4/28/2006 amendment to claim 1 of Application No. 10/837,130.

Instant claim 1 is drawn to a method for treating chronic pain in a subject comprising the step of administering a lentiviral vector comprising a nucleotide of interest to a dorsal root ganglion cell in the subject wherein expression of a nucleotide treats pain in the subject. Claim 1 of conflicting Application 10/837,130 is drawn to a method for treating pain associated with a neurodegenerative disease in a mammal comprising administering a lentiviral vector comprising the nucleic acid sequence of GDNF linked to a promoter, wherein expression of GDNF in the target cell treats the pain associated with the neurodegenerative disease. Instant claim 1 is generic to the method of conflicting claim 1, because a nucleotide of interest is generic to a sequence encoding GDNF, and chronic pain is generic to pain associated with a neurodegenerative disease. It would have been obvious to administer the lentiviral vector comprising the GDNF to a dorsal root ganglion cells because Carpenter teaches that the cells in the dorsal root afferents of the spinal cord (i.e. the central nervous system) contain central processes of ganglion cells related to free nerve endings, tactile, thermal and other somatic and visceral receptors, such as receptors for pain (see page 75, Figure 3.20, and page 76, 1st paragraph). The motivation to use a DRG cell as a target cell in the central nervous system for a pain treatment is the expected benefit of being able to deliver a treatment to the cells that conduct pain sensation.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claims are allowed. Any rejection that has not been discussed herein is withdrawn.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
7/24/2006

DANIEL M. SULLIVAN
PATENT EXAMINER